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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,068	04/14/2004	Chih-Ping Liu	55600-8014.US03	7994

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EXAMINER	
HISSONG, BRUCE D	
ART UNIT	**PAPER NUMBER**
1646	
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Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/825,068	**Applicant(s)** LIU ET AL.	
	Examiner Bruce D. Hissong, Ph.D.	**Art Unit** 1646	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 17 January 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on 17 January 2007. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: 1,3,4,6,8,10 and 11.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

Continuation of 11. does NOT place the application in condition for allowance because:

Rejection of claims 1, 3, 4, 6, 8, 10, and 11 under 35 U.S.C. 112, first paragraph, enablement and written description, is maintained for reasons of record as set forth in the previous office actions. In the reply received on 1/17/2007, the Applicants argue that the instant specification is enabling for methods of increasing the IL-10/IL-12 blood ration in a multiple sclerosis patient, wherein said method comprises adminstering polypeptides that are at least 80% identical to SEQ ID NO: 2. Additionally, the Applicants argue that the instant specificaiton adequately describes the genus of polypeptides with at least 80% identity ot SEQ ID NO: 2 that are capable of increasing the IL-10/IL-12 blood ratio when adminstered to a multiple sclerosis patient. The Applicants specifically argue that IFN-t polypeptides are known in the art, and that a person of ordinary skill in the art would therefore know how to make and use IFN-t polypeptides having less than 100% identity to SEQ ID NO: 2 in a manner that is commensurate in scope with the claims. Additionally, because IFN-t polypeptides are known in the art, and the specificaiton teaches that conservative substitutions/mutations can be made to such polypeptides, a skilled artisan would know how to make such polypeptides, and that furthermore, the specification adequately describes the genus of polypeptides which can be used in the instant invention. These arguments have been fully considered and are not persuasive. As stated in the previous office actions, the claims encompass any polypeptide with at least 80% identity to SEQ ID NO: 2, and thus the claims are drawn to a potentially large number of polypeptides. The specification does not provide guidance or examples showing that all possible IFN-t mutants having at least 80% identity to SEQ ID NO: 1 would be functional in increasing the IL-10/IL-12 blood ratio, and a skilled artisan would not be able to predict which of the many possible IFN-t mutants would do so without further experimentation. Likewise, although IFN-t polypeptides are known in the art, and the specification discloses that conservative substitutions can be made in IFN-t polypeptides, these disclosures by themselves are not sufficient to adequately describe all possible IFN-t polypeptides with at least 80% homology to SEQ ID NO: 2.

Rejection of claims 1, 3, 4, 6, 8, 10, and 11 under 35 U.S.C. 103, as being obvious in view of the combination of Soos, Boxel-Dezaire, and Petereit, is maintained for reasons of record as set forth in the previous office actions. in the reply received on 1/17/2007, the Applicants argue that neither Soos, Boxel-Dezaire, nor Petereit disclose the claimed dosage of IFN-t (SEQ ID NO: 2), nor do these references suggest such a dosage, and therefore the claims are not obvious in view of the cited combination. These arguments have been fully considered and are not persuasive. As set forth in the previous office actions, the combinantion of Soos, Boxel-Dezaire, and Petereit teach administration of IFN-t for treatment of multiple sclerosis, decreased IL-10 levels in multiple sclerosis patients, and a correlation of decreased IL-10 and higher disability scores. Also taught is that administration of IFN-t increases IL-10 levels. Thus, the combined disclosures of these references provides the motivation to administer IFN-t to increase the IL-10/IL-12 blood ratio in multiple sclerosis pateints. Because the combined references do not teach away from the claimed dosage, the results of the instant application would not be unexpected. Furthermore, one of ordinary skill in the art would always have the motivation, and the ability, to optimize the dosage of a therapeutic regime that has already been disclosed in the art as effective for a particular disease.

Claims 1, 3, 4, 6, 8, 10, and 11 remain provisionally rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 17, and 18 of co-pending application 11/112,369, is maintained for reasons of record set forth in the previous office actions. In the response received on 1/17/2007, the Applicants argue that not all multiple sclerosis patients exhibit decreased IL-10 levels, and therefore identifying a multiple sclerosis patient would not inherently identify a patient having an IL-10 deficiency. This argument has been fully considered and is not persuasive. As stated in the previous office actions, it is known in the art that multiple sclerosis patients have decreased IL-10 levels. Even if not all multiple sclerosis patients exhibit IL-10 deficiency, the method of the instant application seeks to adminster IFN-t for the purpose of increasing IL-10 levels. Thus, a skilled artisan would find it obvious to identify patients with IL-10 defiency in the practicing of the instant application. It is also noted that the method steps of adminstering IFN-t in the instant application is identical to those of the '369 application.

Claims 1, 3, 4, 6, 8, 10, and 11 remain provisionally rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over co-pending applications 10/825,382, 10/825,457, 10/824,710, 11/040,706, and 10/884,741. As stated in the previous office action, the Examiner notes Applicants submission of a terminal disclaimer. Upon approval of said terminal disclaimer, the rejection will be withdrawn.

ROBERT S. LANDSMAN, PH.D
PRIMARY EXAMINER